II

106TH CONGRESS
2D SESSION

S. 2520

To amend the Federal Food, Drug, and Cosmetic Act to allow for the importation of certain covered products, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 9, 2000

Mr. JEFFORDS (for himself, Mr. WELLSTONE, Ms. SNOWE, and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow for the importation of certain covered products, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medicine Equity and Drug Safety Act of 2000''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) The cost of prescription drugs for Americans continues to rise at an alarming rate.

(2) Millions of Americans, including medicare beneficiaries on fixed incomes, face a daily choice between purchasing life-sustaining prescription drugs, or paying for other necessities, such as food and housing.

(3) Many life-saving prescription drugs are available in countries other than the United States at substantially lower prices, even though such drugs were developed and are approved for use by patients in the United States.

(4) Many Americans travel to Canada or other countries to purchase prescription drugs because the medicines that they need are unaffordable in the United States.

(5) Americans should be able to purchase medicines at prices that are comparable to prices for such medicines in other countries, but efforts to enable such purchases should not endanger the gold standard for safety and effectiveness that has been established and maintained in the United States.

SEC. 3. IMPORTATION OF COVERED PRODUCTS.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended—

(1) in section 801(d)(1), by inserting ''and section 804'' after ''paragraph (2)''; and

(2) by adding at the end the following:

"SEC. 804. IMPORTATION OF COVERED PRODUCTS.

''(a) REGULATIONS.—

''(1) IN GENERAL.—Notwithstanding sections 301(d), 301(t), and 801(a), the Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting importation into the United States of covered products.

''(2) LIMITATION.—Regulations promulgated under paragraph (1) shall—

''(A) require that safeguards are in place that provide a reasonable assurance to the Secretary that each covered product that is imported is safe and effective for its intended use;

''(B) require that the individual, or pharmacist or wholesaler, importing a covered product complies with the provisions of subsection (b) or (c), as appropriate; and

''(C) contain such additional safeguards as the Secretary may specify in order to ensure the safety of patients in the United States.

''(3) SAFEGUARDS.—In determining safeguards for a covered product under paragraph (2)(C), the Secretary shall consider the adequacy of the regu-

latory structure of the exporting country to ensure the safety and effectiveness of the covered product.

''(4) RECORDS.—Regulations promulgated under paragraph (1) shall require that records regarding importation described in subsections (b) and (c) be gathered and maintained by the Secretary for a period of time determined to be necessary by the Secretary.

''(b) PERSONAL BAGGAGE.—

''(1) IN GENERAL.—The Secretary shall promulgate regulations that permit an individual to import into the United States a covered product in personal baggage.

''(2) REGULATIONS.—Regulations promulgated under paragraph (1) shall require an individual importing a covered product to—

''(A) affirm in writing that the product is for personal use of the individual;

''(B) seek to import an amount of the product appropriate for personal use, such as a 3-month supply; and

''(C) provide to the Secretary—

''(i) the name and address of a health professional licensed to prescribe drugs in the United States that is responsible for

treatment with the product, or evidence that the product is for the continuation of a treatment begun in a foreign country;

''(ii) a description of the product, including the name, the amount being imported, and the price paid for the product;

''(iii) information indicating the destination of the product;

''(iv) information indicating the date on which and the place where the product was purchased;

''(v) the name, address, and telephone number of the importer; and

''(vi) any other information that the Secretary determines is necessary to ensure that the product being imported is safe and effective for its intended use, and to ensure that the Secretary maintains the ability to track an imported product that is found to be counterfeit, expired, subpotent, or otherwise unsafe or ineffective for its intended use.

''(c) REIMPORTATION.—

''(1) IN GENERAL.—The Secretary shall promulgate regulations that permit a pharmacist or

wholesaler to import into the United States a covered product that meets the requirements of sections 501, 502, and 505, and was manufactured in a State and exported, or in an establishment registered under 510.

''(2) REGULATIONS.—Regulations promulgated under paragraph (1) shall require a pharmacist or wholesaler to provide to the Secretary—

''(A) a description of the product, including the name, the amount being imported, and the price paid for the product;

''(B) information indicating the destination of the product;

''(C) information indicating the date on which and the place where the product was purchased;

''(D) the name, address, and telephone number of the importer, and the professional license number of the pharmacist or wholesaler;

''(E) information demonstrating to the satisfaction of the Secretary that the product being imported was manufactured in a State or at an establishment registered under section 510; and

''(F) any other information that the Secretary determines is necessary to ensure that the product being imported is safe and effective.

''(d) STUDY AND REPORT.—

''(1) STUDY.—The Secretary shall conduct, or contract with an entity to conduct, a study on the imports permitted under this section, taking into consideration the information received under subsections (a), (b), and (c). In conducting such study, the Secretary or entity shall evaluate the safety and purity of the products imported, and other patent and trade issues that may have an effect on the safety or availability of such products .

''(2) REPORT.—Not later than 5 years after the date of enactment of this section, the Secretary shall prepare and submit to Congress a report containing the study described in paragraph (1).

''(e) CONSTRUCTION.—Nothing in this section shall be construed to limit the statutory, regulatory, or enforcement authority of the Secretary relating to importation of covered products, other than the importation described in subsections (a), (b), and (c).

''(f) LIMITATION.—Information collected pursuant to this section shall be subject to the provisions of section

522a of title 5, United States Code (commonly known as the 'Privacy Act of 1974').

''(g) DEFINITIONS.—In this section:

''(1) COVERED PRODUCT.—The term 'covered product' means a prescription drug under section 503(b)(1).

''(2) PHARMACIST.—The term 'pharmacist' means a person licensed by a State to practice pharmacy in the United States, including the dispensing and selling of prescription drugs.

''(3) WHOLESALER.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States.''.

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